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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 05 NOV 2004

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Applicant's or agent's file reference 03op133p	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/KR2004/000092	International filing date(day/month/year) 19 JANUARY 2004 (19.01.2004)	Priority date (day/month/year) 23 JANUARY 2003 (23.01.2003)	
International Patent Classification (IPC) or national classification and IPC IPC7 A61K 9/16			
Applicant AMOREPACIFIC CORPORATION et al			

- This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.
- This report is also accompanied by ANNEXES, comprising:
 - ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____ containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).

- This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand 23 JULY 2004 (23.07.2004)	Date of completion of this report 27 OCTOBER 2004 (27.10.2004)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer Yoon, Kyung Ae Telephone No. 82-42-481-5605 

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/000092

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____ as originally filed/furnished
- pages* _____ as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheet _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-13	YES
	Claims	none	NO
Inventive step (IS)	Claims	1-13	YES
	Claims	none	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims	none	NO

2. Citations and explanations (Rule 70.7)

The present invention relates to sustained-release preparations characterized by being prepared from double granules which are obtained by primary granulation of a drug according to melt granulation using hydrophobic release-delaying additives, and then by secondary granulation of the obtained granules according to wet granulation using hydrophobic wet-granulation material.

The following documents have been considered for the purpose of this report:

D1 = WO 99/47128 A1 (23. 09. 1999)

D2 = US 5807583 A (15. 09. 1998)

D3 = EP 1125586 A1 (22. 08. 2001)

D4 = US 2002/102302 A1 (01. 08. 2002)

D5 = US 5451409 A (19. 09. 1995)

D1 discloses a biphasic controlled release delivery system for high solubility pharmaceuticals, which includes an inner solid particulate phase and an outer solid continuous phase.

D2 discloses a process for manufacturing sustained release pellets comprising pelletizing a mixture containing a drug in finely divided form and a water-insoluble wax-like binder.

D3 discloses sustained release particles comprising a drug-containing core substance coated with a mixed coating of a hydrophobic organic compound and water-insoluble polymer, which prevents sticking during compression molding when producing tablets.

D4 describes a stabilized sustained release tramadol tablet containing a hydrophobic material which comprises a wax-like substance.

D5 describes a sustained release matrix and oral dosage form comprising a homogeneous matrix formed from a wet granulation containing a medicament and a polymer blend of HEC and HPC.

(Continued in Supplemental Box)

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Box V.

1. Novelty

None of D1 to D5 relates to sustained-release double granule preparations obtained by primary melt granulation and secondary wet granulation as claimed in the present claims 1 to 13.

Therefore, the subject matter of claims 1-13 can be regarded as novel under PCT Article 33(2).

2. Inventive Step

None of the above-mentioned prior art documents teaches or fairly suggests sustained-release preparations prepared from double granules which are obtained by primary melt granulation and secondary wet granulation using hydrophobic materials such as waxes and fatty acids, nor improved properties of said preparations characterized by minimizing the amount of hydrophobic additives for imparting sustained-releasing property and eliminating an adhesion phenomenon of granules occurring during the tablet preparation. The prior art documents merely refer to sustained-release preparations obtained by either melt or wet granulation. Therefore, the subject matter of claims 1-13 is considered to involve an inventive step under PCT Article 33(3).

3. Industrial Applicability

The subject matter of claims 1-13 is considered to be industrially applicable under PCT Article 33(4).

INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2004/000092**A. CLASSIFICATION OF SUBJECT MATTER****IPC7 A61K 9/16**

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
KOREAN PATENTS AND APPLICATIONS FOR INVENTIONS SINCE 1975Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
CAPLUS(STN), EMBASE(STN), PASCAL(STN), SCISEARCH(STN), WPI, USPATFULL, JAPIO**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99/47128 A1 (BRISTOL-MYERS SQUIBB COMPANY) 23 SEPTEMBER 1999 see the whole document	1, 4, 5
A	US 5807583 A (PHARMACIA AB) 15 SEPTEMBER 1998 see the whole document	1, 4, 5
A	EP 1125586 A1 (TANABE SEIYAKU CO., LTD.) 22 AUGUST 2001 see the whole document	1
A	US 2002/102302 A1 (OSHLACK, B., HUANG, H.-P., CHASIN, M., GOLDENHEIM, P.) 1 AUGUST 2002 see the whole document	1, 4, 5
A	US 5451409 A (RENCHE, W.F., BABU, S., MUSUNURI, S., DAY, C.H., SCHWING, J.) 19 SEPTEMBER 1995 see the whole document	1

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

08 JUNE 2004 (08.06.2004)

Date of mailing of the international search report

08 JUNE 2004 (08.06.2004)

Name and mailing address of the ISA/KR

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/KR2004/000092

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
W09947128A1	23.09.1999	AU3182899A	11.10.1999
		AU736951B2	09.08.2001
		BR9908911A	02.10.2001
		CA2320900A1	23.09.1999
		CN1295467T	16.05.2001
		EA3101B1	26.12.2002
		EP1063973A1	03.01.2001
		JP2002506812T	05.03.2002
		NZ506202A	31.10.2003
US5807583A	15.09.1998	AT154756T	15.07.1997
		AU3911193A	21.10.1993
		CA2132451A1	30.09.1993
		DE69311800D1	31.07.1997
		DE69311800T2	08.01.1998
		DK630235T3	02.02.1998
		EP0630235A1	28.12.1994
		ES2105240T3	16.10.1997
		GR3024604T3	31.12.1997
		JP7505360T	15.06.1995
		SE9200858A	21.09.1993
		W09318753A1	30.09.1993
EP1125586A1	22.08.2001	AU6228799A	15.05.2000
		CA2347104A1	05.04.2000
		CN1331605T	16.01.2002
		W00024423A1	04.05.2000
US20020102302A1	01.08.2002	AU8293498A1	25.01.1999
		CA2270975AA	14.01.1999
		EP1009387A1	21.06.2000
		JP2000510487T2	15.08.2000
		US6306438A	23.10.2001
		W09901111A1	14.01.1999
US5451409A	19.09.1995	NONE	